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Hepatitis A Vaccine, Inactivated
Havrix®

See complete prescribing information in SmithKline Beecham Pharmaceuticals literature. The following is a brief summary.

INDICATIONS AND USAGE: *Havrix* is indicated for active immunization of persons ≥ 2 years of age against disease caused by hepatitis A virus (HAV).

CONTRAINDICATIONS: *Havrix* is contraindicated in people with known hypersensitivity to any component of the vaccine.

WARNINGS: Do not give additional injections to patients experiencing hypersensitivity reactions after a *Havrix* injection. (See CONTRAINDICATIONS.)

Hepatitis A has a relatively long incubation period. Hepatitis A vaccine may not prevent hepatitis A infection in those who have an unrecognized hepatitis A infection at the time of vaccination. Additionally, it may not prevent infection in those who do not achieve protective antibody titers (although the lowest titer needed to confer protection has not been determined).

PRECAUTIONS: As with any parenteral vaccine (1) keep epinephrine available for use in case of anaphylaxis or anaphylactoid reaction; (2) delay administration, if possible, in people with any febrile illness or active infection, except when the physican believes withholding vaccine entails the greater risk; (3) take all known precautions to prevent adverse reactions, including reviewing patients' history for hypersensitivity to this or similar vaccines.

Administer with caution to people with thrombocytopenia or a bleeding disorder, or people taking anticoagulants. Do not inject into a blood vessel. Use a separate, sterile needle or prefilled syringe for every patient. When giving concomitantly with other vaccines or IG, use separate needles and different injection sites.

As with any vaccine, if administered to immunosuppressed persons or persons receiving immunosuppressive therapy, the expected immune response may not be obtained.

Carcinogenesis, Mutagenesis, Impairment of Fertility: *Havrix* has not been evaluated for its carcinogenic potential, mutagenic potential or potential for impairment of fertility.

Pregnancy Category C: Animal reproduction studies have not been conducted with *Havrix*. It is also not known whether *Havrix* can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Give *Havrix* to a pregnant woman only if clearly needed. It is not known whether *Havrix* is excreted in human milk. Because many drugs are excreted in human milk, use caution when administering *Havrix* to a nursing woman.

Havrix is well tolerated and highly immunogenic and effective in children.

Fully inform patients, parents or guardians of the benefits and risks of immunization with *Havrix*. For persons traveling to endemic or epidemic areas, consult current CDC advisories regarding specific locales. Travelers should take all necessary precautions to avoid contact with, or ingestion of, contaminated food or water. Duration of immunity following a complete vaccination schedule has not been established.

ADVERSE REACTIONS: *Havrix* has been generally well tolerated. As with all pharmaceuticals, however, it is possible that expanded commercial use of the vaccine could reveal rare adverse events.

The most frequently reported by volunteers in clinical trials was injection-site soreness (56% of adults; 21% of children); headache (14% of adults; less than 9% of children). Other solicited and unsolicited events are listed below:

Incidence 1% to 10% of injections: Induration, redness, swelling; fatigue, fever (>37.5°C), malaise; anorexia, nausea.

Incidence <1% of injections: Hematoma; pruritus, rash, urticaria; pharyngitis, other upper respiratory tract infections; abdominal pain, diarrhea, dysgeusia, vomiting; arthralgia, elevation of creatine phosphokinase, myalgia; lymphadenopathy; hypertonic episode, insomnia, photophobia, vertigo.

Additional safety data

Safety data were obtained from two additional sources in which large populations were vaccinated. In an outbreak setting in which 4,930 individuals were immunized with a single dose of either 720 EL.U. or 1440 EL.U. of *Havrix*, the vaccine was well-tolerated and no serious adverse events due to vaccination were reported. Overall, less than 10% of vaccinees reported solicited general adverse events following the vaccine. The most common solicited local adverse event was pain at the injection site, reported in 22.3% of subjects at 24 hours and decreasing to 2.4% by 72 hours.

In a field efficacy trial, 19,037 children received the 360 EL.U. dose of *Havrix*. The most commonly reported adverse events were injection-site pain (9.5%) and tenderness (8.1%), reported following first doses of *Havrix*. Other adverse events were infrequent and comparable to the control vaccine Engerix-B® (Hepatitis B Vaccine, Recombinant).

Postmarketing Reports: Rare voluntary reports of adverse events in people receiving *Havrix* since market introduction include the following: localized edema; anaphylaxis/anaphylactoid reactions, somnolence; syncope; jaundice, hepatitis; erythema multiforme, hyperhydrosis, angioedema; dyspnea; lymphadenopathy; convulsions, encephalopathy, dizziness, neuropathy, myelitis, paresthesia, Guillain-Barré syndrome, multiple sclerosis; congenital abnormality.

The U.S. Department of Health and Human Services has established the Vaccine Adverse Events Reporting System (VAERS) to accept reports of suspected adverse events after the administration of any vaccine, including, but not limited to, the reporting of events required by the National Childhood Vaccine Injury Act of 1986. The toll-free number for VAERS forms and information is 1-800-822-7967.

HOW SUPPLIED: 360 EL.U./0.5 mL: NDC 58160-836-01 Package of 1 single-dose vial.

720 EL.U./0.5 mL: NDC 58160-837-01 Package of 1 single-dose vial; NDC 58160-837-02 Package of 1 prefilled syringe.

1440 EL.U./mL: NDC 58160-835-01 Package of 1 single-dose vial; NDC 58160-835-02 Package of 1 prefilled syringe.

Manufactured by **SmithKline Beecham Biologicals**
Rixensart, Belgium
Distributed by **SmithKline Beecham Pharmaceuticals**
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